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Applicants: Robert E. Grove, et al.
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For : PULSED INFRARED LASER TREATMENT OF PSORIASIS

Examiner : A. Sykes
Art Unit : 3305

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Ronald J. Kransdorf, Reg. 20,004

Commissioner of Patents
and Trademarks
Washington, DC 20231

Sir:

RULE 132 AFFIDAVIT

I, Robert E. Grove, aver as follows:

1. I have a B.S. degree (1970) from Cornell University in Engineering Physics, an M.S. degree (1971) from Massachusetts Institute of Technology, Department of Aeronautics and Astronautics, specializing in laser applications, and a Ph.D. (1975) from Massachusetts Institute of Technology, Department of Aeronautics and Astronautics also relating to laser applications.

2. I have worked over the years in various capacities in the medical laser field, including work at Lawrence Livermore National Laboratories as a project leader for copper laser development, as a cofounder of Plasma Kinetics, the world's

first copper laser company, as President of the Laser Products Division and Vice President of Business Development for LaserSonics, a medical laser manufacturer, as a founder of DermaCare, Inc., a health care service corporation, and as a founder of Star Medical Technologies, the assignee of the above-identified application. In these various positions, I have worked in the laser treatment of vascular malformations and dermatology problems and have a high level of expertise in these fields. I am also one of the coinventors on the above-identified application.

3. In February, 1993, when the above-identified patent application was filed, the conventional thinking was that, in order to destroy blood vessels or some other target within a person's body, the laser used for the procedure should operate at a wavelength which is preferentially absorbed by such target. I am familiar with U.S. Patent No. 4,733,660 to Itzkan and U.S. Patent No. 5,217,455 to Tan, both of which reflect the conventional wisdom discussed above. In particular, since blood, as is shown in Fig. 2 of the above-identified application, absorbs significant energy at wavelengths below 600 nm, and is roughly two orders of magnitude less absorbent at higher wavelengths, Itzkan teaches operating at a wavelength below 600 nm for the selective necrosis of blood vessels, while leaving adjacent tissue undamaged. Similarly, Tan is concerned with destroying tattoos, and in particular, the pigment of tattoos, while achieving minimal damage to surrounding tissue. Tan therefore operates at a wavelength where the tattoo pigments are highly absorbent to maximize damage to the tattoos, but where the blood vessels are not highly absorbent so as to minimize damage to blood vessels and surrounding tissue.

4. At the time my coinventor and I started our work, we were aware of prior art treatment techniques such as those of Tan and Itzkan, and were also aware of the work of Rasmussen in attempting to treat psoriasis by destroying blood vessels with lasers operating substantially as taught in Itzkan. The work of Rasmussen had met with only limited success and we concluded that one reason for this was that there was a need to destroy deep blood vessels, for example blood vessels at depths of up to 1 mm. However, because of the high absorption of blood at wavelengths below 600 nm, it was not possible using the techniques of Itzkan to achieve significant damage of blood vessels at depths much beyond 0.5 mm unless the power of the laser was so high as to cause significant damage to overlying skin.

5. While we were aware of the work of Tan at wavelengths above 600 nm, this work did not involve the destruction of blood vessels, and nothing in our prior knowledge or experience suggested that lasers operating at a wavelength in excess of 600 nm could be used for the destruction of any blood vessels, far less blood vessels at significant depths.

6. However, after careful analysis, we concluded that, even though blood is not highly absorbent at wavelengths in the 700-1100 nm range, it is significantly more absorbent than other materials through which the laser beam would be passing. Thus, in spite of blood's low absorption at these wavelengths, it would in fact absorb a substantial fraction (roughly half) of the energy in the laser beam; and since blood accounts for only 2-8% of the dermal tissue volume, the illuminated blood vessels would be raised to a temperature much higher than the surrounding tissue. Further, because of the low absorption of blood in the surface vessels, more energy could pass to the greater depths, permitting absorption of laser energy by the

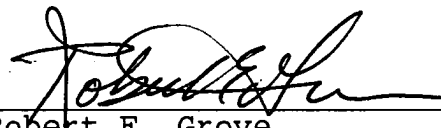
deeper blood vessels. After careful calculation and experimentation, we concluded that destruction of deep blood vessels could be achieved with a laser operating in a wavelength between 700 nm and 1100 nm if the laser were pulsed and designed so as to deliver a fluence at the skin surface of between 5 joules per square centimeter and 50 joules per square centimeter, with each pulse having a pulse duration between 0.2 ms and 20 ms. This pulse duration is significantly longer than that used by Tan and is required by the lower absorption of blood at these wavelengths, in order for sufficient energy to be absorbed by the blood vessels to achieve the desired necrosis without the use of excessive peak powers which can cause vessel rupture.

7. As ones skilled in the art, my colleagues and I were not aware at the time of our invention of any suggestion in the art that blood vessels could be selectively destroyed by use of laser energy in the 700-1100 nm range, and this was clearly contrary to conventional thinking at such time. In particular, there was nothing in the art to suggest that lasers operating in this wavelength range could be used for the selective necrosis of deep blood vessels and the fact that this could be achieved was determined only through research and experimentation. Finally, there was nothing in the art to suggest the fluences and pulse durations for a laser operating in the 700-1100 nm range which might be used to achieve the necrosis of blood vessels, and these values were also arrived at only by calculation and experimentation.

8. Based on the above, it was not obvious to us as ones skilled in the art in view of prior art known to us at the time we began our work, including art such as Itzkan and Tan, that deep necrosis of blood vessels by a laser could be achieved or

that such deep necrosis could be achieved by a laser operating at the wavelengths and with the fluences and pulse durations set forth in the claims of the above-identified application.

Further, based on the knowledge and experience set forth above, it is my opinion that the invention would not have been obvious to others skilled in the art and this is the reaction I have received from others skilled in the art with whom I have discussed the invention.

DATE: 3/2/95
Robert E. Grove

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